(iii) an isolated nucleic acid molecule encoding a protein comprising an amino acid sequence 95% identical to the SEQ of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, wherein said protein binds a canine IL-13 protein;

(iv) an isolated nucleic acid molecule encoding a protein comprising an at least 40 contiguous amino acid region identical in sequence to an at least 40 contiguous amino acid region from SEQ of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, wherein said protein binds a canine IL-13 protein; and

(v) an isolated nucleic acid molecule fully complementary to the isolated nucleic acid molecule of (i), (ii), (iii) or (v); and

(b) recovering said canine IL-13Rα2 protein.

REMARKS

The previous title was canceled and a new title which more accurately describes the invention has been submitted.

Claims 24, 25, 28-30, 34-40, 43-47, 49-51, 53 and 54 have been canceled and new claims 60-80 have been submitted for examination. Applicants submit the newly submitted claims substantially track the canceled claims.

Specifically, new claim 60 substantially tracks previous claim 24 except that the limitation of '40 nucleotides' in claim 24 part (a), has been changed to '50 nucleotides' in claim 60. Likewise, the limitation of '80% identical' in claim 24, part (b), has been changed to read '95% identical' in claim 60. In addition, the limitation '50 nucleotides in length' has been changed to '60 nucleotides in length' and a functional limitation (IL-13 binding) has been added. Support for the specific nucleotide lengths and nucleic acid molecules '95% identical' can be found, for example, in the specification on page 34, lines 20-31, through page 35, lines 1-20. Support for IL-13 binding activity can be found, for example, on page 38, lines 11-13. Furthermore, the phrase 'at least 40 contiguous nucleotide region' has been changed to 'an at least 50 contiguous nucleotide region'. Additionally, claim 60, in particular part (c), has been drafted to include nucleic acids complementary in sequence to the nucleic acid molecules of part (a) and part (b). Support for such complementary nucleic acid molecules can be found, for example, in

the specification on page 13, lines 27-31, through page 14, lines 1-2. Finally, language reciting a particular algorithm has been removed in an effort to simplify the claim.

New claim 62 substantially tracks previous claim 24, in particular part (b), except the limitation of "80% identical' to a full length sequence has been changed to '95% identical' in claim 60. In addition, a functional limitation, namely IL-13 protein binding, has been added to the language of the claim. Support for these changes can be found in the specification as stated above.

New claim 63 substantially tracks previous claims 28 and 29, except the limitation of '70% identical' in claim 28, part (a)(i), has been changed to '95% identical' in new claim 63. Support for proteins '95% identical' can be found, for example, in the specification on page 54, lines 6-15. In addition, language reciting a particular algorithm has been removed in an effort to simplify the claim. Finally, the claim language of previous claim 29 has been incorporated into new claim 63, part (a)(i) adding a functional limitation (IL-13 binding) to the proteins encompassed by the language of that section.

New claim 64 substantially tracks previous claim 34, except the limitation of '30 contiguous amino acids' in claim 34, part (a), has been changed to '50 contiguous amino acids' in new claim 64. Support for protein fragments of '50 amino acids' can be found, for example, in the specification on page 54, lines 27-31, through page 55, lines 1-2. In addition, the limitation '70% identical' has been changed to '95% identical' in new claim 34, part (b). Finally, a functional limitation (IL-3 binding) had been added to the claim language of claim 64, part (b).

New dependent claim 65 adds the limitation that the protein of claim 64 must comprise a stated amino acid sequence.

New claim 66 substantially tracks previous claim 36, except the term 'canine IL-13Rα2 protein domain' has been more clearly defined and a functional limitation has been added to the language of the claim. Support for the language of claim 66 can be found, for example, in the specification on page 58, lines 3-31 through page 59, lines 1-22.

New claim 80 substantially tracks previous claim 54, except the new claim lists specific IL-13Rα sequences used for expression. In addition, a purification step has been added to the stated method. Support for purification of the stated proteins can be found, for example, in the specification on page 64, lines 6-20.

The remaining claims substantially track the previous claims but have been given new claim numbers in order keep the claims in a logical order. In some cases, minor changes have been made to clarify the meaning of the claim. For the convenience of the Examiner, the chart below relates the relationship between the previous claims and the corresponding new claim.

New Claim Number	Previous Claim Number	Comments
61	25	
66	36	language changed to for clarity; SEQ ID NO's added to define IL-13αR2 protein; functional limitation added
67	37	
68	38	
69	39	
70	40	the word 'gamma' was included for clarity
71	43	
72	44	wording rearranged for clarity
73	45	wording rearranged for clarity
74	46	wording rearranged for clarity
75	47	
76	49	
77	50	
78	51	preamble simplified; mimetope & multimeric protein language removed
79	52	

In view of the support noted above, Applicants contend no new matter has been entered into the Application.

I. Formal Matters

The Examiner has stated the Application title originally submitted is not descriptive of the invention. Applicants have canceled the original title and submitted a new title which more accurately describes the instant invention.

The Examiner has objected to claims 24, 28 and 34, stating the claims are confusing for repeated use of 'first', 'second', 'third', etc. to refer to proteins and nucleic acid molecules. Applicants note that all pending claims have been canceled and new claims submitted. In

drafting the new claims, Applicants have mitigated or avoided using the above terms in an effort to simplify the claim language.

II. Rejections under 35 U.S.C. §112, second paragraph

The examiner has rejected claims 24, 25, 28-30, 34-40, 43-47 and 49-51 as being indefinite for failing to point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the major objection raised by the Examiner relates to the wording of the above-mentioned claims with regard to, for example, antecedent basis and the use of 'first', 'second' and 'third' in referring to proteins and nucleic acid sequences. Further, the Examiner states that in previous claim 36, the limitation 'canine IL-13Rα2 protein domain' is indefinite since the protein is referred to only by name and the claim lacks any associated structural limitation. Applicants note that all of the above claims have been canceled and newly drafted, but related, claims have been submitted. Applicants believe the newly drafted claims avoid the apparent lack of clarity noted by the Examiner in the previous claims set. With regard to claim 36, now substantially replaced by new claim 66, Applicants note that SEQ ID NO:'s have been added to provide a structural limitation, as has a requirement for a functional limitation.

III. Rejections under 35 U.S.C. §112, first paragraph

The Examiner has rejected previous claims 24, 28, 29, 34, 35 and 51 under 35 U.S.C. §112, first paragraph, stating that while the specification is enabling for "...nucleic acids disclosed as SEQ ID NO:54, 56, 57, 59, 60, 62-65, 67, 68 or 70 or fragments thereof (of specific lengths) or species which vary by codon degeneracy therefrom, as well as with proteins encoded thereby or fragments of said proteins that retain binding function...", it is not enabling for any nucleic acids only 80% identical to a 50 nucleotide fragment of any of said sequences. The Examiner notes that claims 24 and 34 encompass nucleic acids only 80% identical to a 50 nucleotide fragment of specified SEQ ID NO:'s and proteins 70% identical to a 40 amino acid segment from specified SEQ ID NO:'s, respectively, and further, lack any functional requirement. The Examiner contends that to practice the invention in scope with the claims would require undue experimentation. The Examiner further states that although the relative skill in the art of recombinant DNA technology is high, little is known about the structure-

function relationship in the disclosed proteins and the art of altering proteins is an uncertain one. Additionally, the Examiner states that although there exists art-recognized procedures for producing and screening active muteins, this is not adequate guidance, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. The Examiner has also objected to the use the term mimetopes stating the specification does not disclose how to make mimetopes and therefor enablement is not commensurate in scope with the claims. Finally, the Examiner has rejected claim 30 for lack of written description, stating the limitation that the claimed nucleic acid molecules *not* hybridize to the human and murine IL-13R nucleic acid molecules represents a functional limitation, and that no such molecules are disclose in the specification.

While Applicants respectfully disagree with the objections raised by the Examiner, in the interest of expediting prosecution of this Application, the Applicants have canceled all of the previously pending claims and submitted a new claim set, drafted in view of the Examiners comments. In particular, the percent identity values in all of the new claims have been raised to 95%. In addition, a functional limitation has been added to claims where the Applicants believed necessary. Applicants note the newly submitted claims have been drafted to be in accordance with the Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, P1, Written Description Requirement, published by the U.S. Patent Office. (Federal Register Vol.66, No.4, January 5, 2001). Furthermore, the term 'mimetope' has been removed from all of the newly drafted claims. Applicants note that although the newly submitted claims amend the language of the previously submitted claims, such amendments are not an admission that the Applicants view the previous claims as unpatentable or not supported by the specification, but instead, amendments were made simply in the interest of expediting prosecution of the instant Application. Applicants reserve the right to pursue broader coverage of this subject matter in any future or related filings.

IV. Rejections under 35.U.S.C., §102(b)

The Examiner has rejected claims 24, 28 and 51 under 35 U.S.C. §102(b) as being anticipated by Collins et al., U.S. Patent Number 5,710,023 and by Guo et al., Genomics 42:141, Caput et al., J.B.C. 28:16921, Locus AI798934 or Locus AA298563. Specifically, the Examiner states the references disclose sequences 80% identical to 50 nucleotides of SEQ ID NO:60

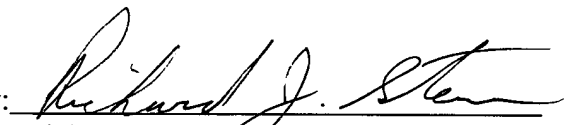
meeting the limitation of claim 24. Further, the protein of Collins , at least, would be considered a mimetope of SEQ ID NO:60 meeting the limitation of claim 51.

Applicants note that all of the rejected claims have been canceled and a new claim set submitted. Applicants further note that in the newly submitted claims, the percent identities have been raised to 95%. In addition, in claim 60, which substantially tracks claim 24, the length of the region over which identity must hold has been changed from 50 nucleotides to 60 nucleotides. Applicants believe the new claim set should be free of the prior art.

In light of the remarks above, Applicants believe all of the newly submitted claims are in condition for allowance and solicit an allowance from the Examiner. Should any issues remain unresolved, or should the Examiner have any questions regarding this Application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Dated: January 21, 2003

By: 

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VERSION WITH MARKINGS SHOWING CHANGES

The previous title was canceled and the following title submitted:

"CANINE IL-13 RECEPTOR NUCLEIC ACID MOLECULES, PROTEINS, COMPOSITIONS THEREOF AND METHODS OF USE"

All pending claims have been canceled and the following new claims submitted:

60. (New) An isolated nucleic acid molecule selected from the group consisting of:

(a) an isolated nucleic acid molecule having an at least 50 contiguous nucleotide region identical in sequence to an at least 50 contiguous nucleotide region from SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67, SEQ ID NO:68 or SEQ ID NO:70;

(b) an isolated nucleic acid molecule comprising an at least 60 nucleotide region that is at least 95% identical in sequence to an at least 60 contiguous nucleotide region from SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67, SEQ ID NO:68 or SEQ ID NO:70, wherein said isolated nucleic acid molecule encodes a protein that binds a canine IL-13 protein; and

(c) an isolated nucleic acid molecule fully complementary to the isolated nucleic acid molecule of (a) or (b).

61. (New) The isolated nucleic acid molecule of claim 60, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence encoding an amino acid sequence selected from SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69.

62. (New) The isolated nucleic acid molecule of claim 60, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence 95% identical to the sequence of SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67, SEQ ID NO:68 or SEQ ID NO:70, and wherein said isolated nucleic acid sequence encodes a protein that binds a canine IL-13 protein.

63. (New) An isolated nucleic acid molecule selected from the group consisting of:

(a) an isolated nucleic acid molecule encoding a protein selected from the group consisting of:

(i) a protein comprising an amino acid sequence 95% identical to the sequence of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, wherein said protein binds a canine IL-13 protein; and

(ii) a protein comprising an at least 40 contiguous amino acid region identical in sequence to an at least 40 contiguous amino acid region from SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69; and

(b) an isolated nucleic acid molecule fully complementary to an isolated nucleic acid molecule of (a).

64. (New) An isolated protein selected from the group consisting of:

(a) a protein comprising an at least 50 contiguous amino acid sequence to an at least 50 contiguous amino acid sequence from SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, wherein said protein binds a canine IL-13 protein; and

(b) a protein comprising an amino acid sequence that is at least 95% identical in sequence to SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, wherein said protein binds a canine IL-13 protein.

65. (New) The isolated protein of claim 64, wherein said isolated protein comprises an amino acid sequence selected from SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69.

66. (New) A chimeric nucleic acid molecule encoding a fusion protein comprising a carrier protein domain and a canine IL-13Rα2 protein domain, wherein said canine IL-13Rα2 protein domain comprises an at least 40 contiguous amino acid region identical in sequence to an at least 40 contiguous amino acid region from SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61,

SEQ ID NO:66 or SEQ ID NO:69, and wherein said canine IL-13Rα2 protein domain binds a canine IL-13 protein.

67. (New) The chimeric nucleic acid molecule of claim 66, wherein said fusion protein comprises a linker sequence.

68. (New) The chimeric nucleic acid molecule of claim 66, wherein said carrier protein domain is an immunoglobulin Fc region.

69. (New) The chimeric nucleic acid molecule of claim 66, wherein said carrier protein domain is a canine immunoglobulin Fc region.

70. (New) The chimeric nucleic acid molecule of claim 66, wherein said carrier protein domain is a canine immunoglobulin gamma Fc region.

71. (New) The chimeric nucleic acid molecule of claim 66, wherein said chimeric nucleic acid molecule comprises a nucleic acid sequence selected from the group consisting SEQ ID NO:71, SEQ ID NO:74, SEQ ID NO:77, SEQ ID NO:80 and SEQ ID NO:82.

72. (New) The chimeric nucleic acid molecule of claim 66, wherein said IL-13Rα2 protein domain is encoded by nucleic acid sequence selected from the group consisting of SEQ ID NO:54, SEQ ID NO:57, SEQ ID NO:60, SEQ ID NO:63, SEQ ID NO:65 and SEQ ID NO:68.

73. (New) The chimeric nucleic acid molecule of claim 66, wherein said carrier protein domain is encoded by the 5' end of the nucleic acid molecule and said IL-13Rα2 protein domain is encoded by the 3' end of the nucleic acid molecule.

74. (New) The chimeric nucleic acid molecule of claim 66, wherein said IL-13Rα2 protein domain is encoded by the 5' end of the nucleic acid molecule and said carrier protein domain is encoded by the 3' end of the nucleic acid molecule.

75. (New) A fusion protein comprising a carrier protein domain and a canine-IL-13Rα2 protein domain.

76. (New) The fusion protein of claim 75, wherein said fusion protein comprises an amino acid sequence selected from the group consisting of SEQ ID NO:72, SEQ ID NO:75, SEQ ID NO:78 and SEQ ID NO:81.

77. (New) The fusion protein of claim 75, wherein said IL-13Rα2 protein domain comprises an amino acid sequence selected form the group consisting of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61 and SEQ ID NO:66 and SEQ ID NO:69.

78. (New) A therapeutic composition comprising a nucleic acid molecule comprising a nucleic acid molecule encoding a protein selected from a canine IL-13Rα2 protein and the fusion protein of claim 75.

79. (New) A method to regulate an immune response in a canid, said method comprising administering to said canid the therapeutic composition of claim 78.

80. (New) A method to produce a canine IL-13Rα2 protein, said method comprising:

(a) culturing a cell comprising a recombinant nucleic acid molecule selected from the group consisting of:

(i) an isolated nucleic acid molecule having an at least 50 contiguous nucleotide region identical in sequence to an at least 50 contiguous nucleotide region from SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67, SEQ ID NO:68 or SEQ ID NO:70;

(ii) an isolated nucleic acid molecule comprising an at least 100 nucleotide region that is at least 95% identical in sequence to an at least 100 contiguous nucleotide region from SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:63, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:67,

SEQ ID NO:68 or SEQ ID NO:70, wherein said isolated nucleic acid molecule encodes a protein that binds a canine IL-13 protein;

(iii) an isolated nucleic acid molecule encoding a protein comprising an amino acid sequence 95% identical to the SEQ of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, wherein said protein binds a canine IL-13 protein;

(iv) an isolated nucleic acid molecule encoding a protein comprising an at least 40 contiguous amino acid region identical in sequence to an at least 40 contiguous amino acid region from SEQ of SEQ ID NO:55, SEQ ID NO:58, SEQ ID NO:61, SEQ ID NO:66 or SEQ ID NO:69, wherein said protein binds a canine IL-13 protein; and

(v) an isolated nucleic acid molecule fully complementary to the isolated nucleic acid molecule of (i), (ii), (iii) or (v); and

(b) recovering said canine IL-13Rα2 protein.